

Amendments to the Claims

Claims 28-32 have been canceled.

Claims 3, 18, 20, 24 and 33-35 have been amended.

Claims 3, 20, 24 and 33-35, as amended, recite treating psoriasis and do not recite "TNF α -mediated". Support is found in the specification, for example at page 57, line 17 to page 59, line 14, particularly page 58, lines 1-4. In addition, support is found in priority application US Serial No. 07/670,827, filed March 18, 1991, at page 39, line 24 to page 40, line 4.

Further, Claims 3, 20 and 33, as amended, recite treating a human in need thereof. Support is found in the specification, for example at page 57, line 17 to page 59, line 14, particularly page 58, lines 1-4. In addition, support is found in priority application US Serial No. 07/670,827, filed March 18, 1991, at page 39, line 24 to page 40, line 4.

Claim 18 has been amended to recite the method of Claim 17 wherein said single or divided dose is one selected from 0.5, 0.9, 1, 1.1, 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 mg/kg per day on at least one of day 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29 or 30 or at least one of week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20. Support is found in the specification, for example, at page 60, lines 15-24. In addition, support is found in the specification of priority application US Serial No. 07/943,852, filed September 11, 1992, for example, at page 42, lines 5-18.

No new matter has been added by the amendments. Therefore, entry of the amendments into the application is respectfully requested.

Examiner Interview

Applicants thank the Examiner for the conference call on June 6, 2006, in which he provided clarification of the outstanding Office Action. Applicants note that in the Office Communication dated April 10, 2006, the Examiner states that Applicants' Amendment filed January 26, 2006 was entered, but that the claims, as amended, were drawn to generic non-elected inventions. Subsequently, in the Office Action dated May 19, 2006, the Examiner issued a Restriction Requirement.

In order to ensure that Applicants are fully responsive, Applicants are hereby responding to the Restriction Requirement and filing an Amendment in which Applicants maintain their arguments regarding priority and obviousness as argued in the Amendment filed on May 24,

2005 and maintain their arguments regarding enablement and indefiniteness as argued in the Amendment filed on January 26, 2006. Applicants have summarized May 24, 2005 and January 26, 2006 arguments below.

REPLY TO ELECTION OF SPECIES REQUIREMENT

Responsive to the requirement for an election of species for searching purposes dated May 19, 2006, Applicant hereby elects psoriasis. Thus, Claims readable on this elected species are Claims 3, 14-15, 17-18 and 20-27 and 33-35.

Priority

As stated in the Amendment filed on May 24, 2005, Applicants maintain that the instant claims are entitled to claim the benefit of priority application USSN 07/670,827 (filed March 18, 1991). Priority application USSN 07/670,827 provides sufficient written description and enablement for treating TNF α -mediated human disease, including psoriasis. USSN 07/670,827 discloses that the "[h]igh affinity chimeric anti-TNF α mAbs of the present invention, which have potent TNF α neutralizing activity, including TNF α -neutralizing fragments thereof, are useful as therapeutic agents for TNF α -mediated human disease...." (page 10, line 22-25) This priority application teaches treatment of a representative number of species of the genus of "TNF α -mediated diseases," including "rheumatoid arthritis," "Crohn's disease," "sarcoidosis" and "alcohol-induced hepatitis." (page 10, line 22 to page 11, line 4) In addition, the specification of this priority application enables treatment of "TNF α -mediated diseases" and "chronic inflammatory diseases" with the claimed antibodies. (See USSN 07/670,827 at page 39, line 20 to page 40, line 9 and page 10, lines 22 to page 11, line 4))

Psoriasis is a TNF α -mediated disease. For a clear understanding of the definition of psoriasis, please see Fauci, A. S. et al., Harrison's Principles of Internal Medicine 300 (McGraw-Hill, 14th ed. 1998) (hereinafter "Harrison's"), which was attached as Exhibit A in the Amendment filed on February 25, 2004. Harrison's teaches that psoriasis is a chronic inflammatory disease. Although there is not a specific example in the 07/670,827 specification directed to treatment of TNF α -mediated psoriasis, the mechanism of treatment would be the same regardless of the TNF α -mediated disease.

Therefore, the priority application 07/670,827 provides sufficient written description and enablement for treating psoriasis, and Applicants are entitled to claim the benefit of it. This priority application has been properly referenced on page 1 of the specification in compliance with 35 U.S.C. § 120.

Further, at the very least, Applicant's are entitled to priority to March 18, 1992. Applicants note that the Examiner cited Applicants' own PCT application Le *et al.* (WO 92/16553) as prior art. Applicants' PCT application is substantially identical to the corresponding U.S. priority application (USSN 07/853,606) of the subject application, which was filed on the same date as the PCT application (March 18, 1992).

Therefore, if Applicant's disclosure in the PCT application (WO 92/16553) is sufficient to qualify as prior art, then Applicants' disclosure in the March 18, 1992 U.S. priority application (USSN 07/853,606) is sufficient to support the claims, and the claims, at the very least, are entitled to the benefit of priority to the filing date of March 18, 1992.

As discussed above, the instant claims are entitled to claim the benefit of priority application USSN 07/670,827 (filed March 18, 1991), because it provides sufficient written description and enablement for treating psoriasis, a TNF α -mediated human disease.

Enablement of Claims 3, 14-15, 17-18 and 20-35 Under 35 U.S.C. § 112, first paragraph

As stated in Applicants' Amendment filed on January 26, 2006, in order to expedite prosecution, and in accordance with 37 C.F.R. § 1.809 (b)(1), on September 22, 2005, Applicants deposited the cell line for the A2 antibody (designation c134A) with American Type Culture collection (ATCC) under the Budapest Treaty. The ATCC accession number is PTA-7045.

In the Amendment filed January 26, 2006, the specification at page 25, lines 16-23 was amended to recite "As examples of antibodies according to the present invention, murine mAb A2 (ATCC Accession No. PTA-7045) of the present invention is produced by a cell line designated c134A." The specification at page 25, lines 16-23 had been further amended to recite "c134A was deposited pursuant to the Budapest Treaty requirements with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209, on September 22, 2005."

Further, Claims 28-32 have been cancelled. Applicants reserve their rights to file continuing or divisional applications to pursue these claims. In the Amendment filed January 26,

2006, the claims had been amended to delete reference to cA2, and to recite "ATCC Accession No. PTA-7045" for the cell line of the A2 antibody.

Support for the amendments and the deposit of the cell line for the A2 antibody is found in the specification, for example, at page 25, lines 16-23. In addition, support is found in the priority application US Serial No. 07/670,827, filed March 18, 1991, at page 19, lines 14-20.

On January 26, 2006, Applicants filed is a Statement Under 37 C.F.R. §1.804, §1.806 and §1.808.

Reconsideration and withdrawal of the rejection are respectfully requested.

Definiteness of Claims 3, 14-15, 17-18 and 20-35 Under 35 U.S.C. § 112, second paragraph

In order to further prosecution, as discussed above, Claims 28-32 have been canceled. In the Amendment filed January 26, 2006, the claims had been amended to delete reference to cA2, and to recite "ATCC Accession No. PTA-7045" for the cell line of the A2 antibody. As discussed above, on September 22, 2005, Applicants deposited the cell line for the A2 antibody with ATCC under the Budapest Treaty. In the Amendment filed January 26, 2006, the specification at page 25, lines 16-23 had been amended to recite the ATCC accession number, the date of deposit, a description of the biological material and the name and address of the depository.

Reconsideration and withdrawal of the rejection are respectfully requested.

Nonobviousness of Claims 3, 14-15, 17-18 and 20-35 Under 35 U.S.C. § 103(a)

For the reasons of record in the Amendment filed on May 24, 2005, and for the reasons described herein with regard to priority, Applicants maintain that *Le et al.* (WO 92/16553) and *Adair et al.* (U.S. Patent No.: 5,994,510) are not prior art because the priority date of the subject application (March 18, 1991) precedes the date that *Le et al.* and *Adair et al.* would be effective as prior art.

Thus, reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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